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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,099	08/23/2001	Rajiv Indravadan Modi	CAPH 8016US	2239

7590 08/12/2004

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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,099

Applicant(s)

MODI ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18, 22, 23 and 25-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18, 22, 23 and 25-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-15, 18, 22, 23, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific microorganisms listed in claim 3 and the specific anti-infective agents listed in claim 2, does not reasonably provide enablement for any and all anti-infective agents "capable of causing adverse effects caused by destruction of commensals" and any and all microorganisms susceptible to the anti-infective agent or useful in the prevention or minimizing the adverse effects of the anti-infective agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant's specification provides enablement for the specifically claimed anti-infective agents (see claims 2) and microorganisms (see claim 3). Applicant's

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specification does not provide support to claim any and all anti-infective agents and any and all microorganisms "susceptible" to the anti-infective agents. First of all, what is meant by "susceptible" ? The word susceptible is very broad in meaning. One would not necessarily know which microorganisms are susceptible to the anti-infective agent. One can be susceptible to a cold, but that does not mean that one will get a cold. Applicants have shown that list of specific antibiotics work with a specific set of microorganisms. For applicant to claim such broad lists of these is simply without merit since one of ordinary skill in the art would not be able to identify all of the species in these genera. Knowing only these specific microorganisms and these specific antibiotics would at best produce a short list of possible combinations, but how can applicant expect one of ordinary skill in the art to figure out each and every microorganism that might be susceptible to the anti-infective agents. Furthermore, just about every microorganism would be susceptible to an anti-infective agent since the term "susceptible" is vague and indefinite to begin with.

Also, it is important to note that the field of biotechnology is so unpredictable that one would not necessarily know if any and all microorganisms susceptible to the anti-infective would work. Microorganisms are living beings and are therefore, by definition unpredictable and cannot be relied upon to necessarily work with antibiotics to yield applicants results as disclosed in the instant specification.

There is no support for anti-infective agents "capable of causing adverse effects caused by destruction of commensals". Where in the specification is such support found ? These claims are simply too broad.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 18, 22, 23, 25-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record and for the reasons which follow.

Claim 1 is still very confusing. It is now not clear what is meant by "it" in line 9 of claim 1 and similarly in the other claims like claim 25, line 6. It might be clearer to put in the place of "it", "the at least one of the anti-infective agent and the microorganism".

What is mean by "susceptible" ? This term is vague and indefinite. One may be susceptible to a cold but that does not mean that one will get one. Microorganisms are susceptible to all kinds of problems and antibiotics are no exception. One would not necessarily know which microorganisms are susceptible to the anti-infective agent.

What is an anti-infective agent "capable of causing adverse effects caused by destruction of commensals" or microorganisms "useful in the prevention or minimizing the adverse effects of the anti-infective agent". These are terms which really have no art recognized meanings. Unless applicant puts in the specific types of microorganisms and

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anti-infective agents used as shown in the instant specification, these claims as they are written are not understood.

Claim Rejections - 35 USC § 102

Claims 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 6855.

The reference is of record. It teaches using tetracycline which is a known antibiotic. Such an antibiotic would perform the claimed characteristics. Applicant argues that this reference teaches that the microorganism is not susceptible to the anti-infective agent. Applicant provided Finch. Even Finch admits that streptococci are susceptible to tetracycline. Thus, applicant's arguments really are without merit.

Further, as noted before by Hawley's, tetracycline is a known antibiotic and the last time the examiner checked, *lactobacillus* and the others were bacteria.

Claims 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 5247.

The reference is of record. It teaches using tetracycline which is a known antibiotic. Such an antibiotic would perform the claimed characteristics.

Applicant relies on the same arguments as above. Thus, the response is the same as above.

Claim Rejections - 35 USC § 103

Claims 1-15, 18, 22, 23, 25-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 5247 in view of FR 6855 and further in view of Black et al.

Applicant argues essentially the same as above. Black was cited to show that ampicillin is also well known to be used for the same purpose as in the disclosed invention. One of ordinary skill in the art would have been motivated to use ampicillin instead of tetracycline since Black yielded such beneficial results.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Black was used as part of the 35 USC 103 rejection and was not used under 35 USC 102 as argued by applicant. Applicant cannot expect Black to contain all of applicant's invention. It was used as a secondary reference which is clear from the record.

It is clear from Black that it was known that ampicillin was known to be combined with the claimed microorganisms for the known purpose. The two French references each teach that to separate the ingredients and put a barrier between them would have been well known to one of ordinary skill in the art. Thus, to put ampicillin and the

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claimed microorganism together in the same tablet would have been obvious since it was well known to provide a barrier between the two ingredients and to administer them at the same time in the same tablet as taught by the French references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
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MVM